

Many challenges exist in clinical research with regard to the process and manner in which informed consent is obtained. This is especially problematic in developing countries like South Africa (van Loon & Lindegger, 2009:1). One such challenge manifest from the discrepancies and contradictions in the guidance documents and legislation that all clinical researchers in South Africa have to follow and adhere to. In this book the process and manner in which voluntary informed consent is obtained in clinical research is compared from an ethical perspective and in terms of the different guidance documents and relevant governing legislation currently effective and authoritative in the area of clinical and health research in South Africa. It was concluded that the South African specific guidance documents require urgent revision to be in line with each other and other international guidance documents and South African governing legislation and regulations in order to serve a good purpose to, legally and morally, protect South Africans better against research exploitation.



Retha Britz
Andra le Roux-Kemp

Retha Britz is involved in clinical research since 1999. She is currently a clinical research consultant and facilitates GCP courses and informed consent workshops. Dr. Andra le Roux-Kemp is an Assistant Professor at the School of Law, City University of Hong Kong and a Visiting Research Fellow at the School of Law, University of the Witwatersrand

Clinical Research Conduct in South Africa: Informed Consent



978-3-659-62501-5

 **LAMBERT**
Academic Publishing